

## leuprolide acetate (Fensolvi)

### Commercial Medical Benefit Drug Policy

#### Place of Service

Office Administration  
Infusion Center Administration  
Home Infusion Administration  
Outpatient Facility Administration

#### **Drug Details**

**USP Category:** HORMONAL AGENTS, SUPPRESSANT (ADRENAL OR PITUITARY)

**Mechanism of Action:** Gonadotropin releasing hormone (GnRH) agonist

#### **HCPCS:**

J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg

#### **How Supplied:**

45 mg of leuprolide acetate supplied in a kit

#### **Condition(s) listed in policy** *(see coverage criteria for details)*

- Central Precocious Puberty
- Gender Dysphoria in Adolescents

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

#### **Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

**The following condition(s) DO NOT require Prior Authorization/Preservice if ALL its parameters are met, otherwise Prior Authorization/Preservice is required.**

#### **Central Precocious Puberty**

1. Documented diagnosis of central precocious puberty (neurogenic or idiopathic)

#### **Covered Doses:**

Not to exceed 45 mg given subcutaneously once every six months

#### **ICD-10:**

E30.1

#### **Gender Dysphoria in Adolescents**

**Covered Doses:**

Not to exceed 45 mg given subcutaneously once every six months

**ICD-10:**

F64.0, F64.1, F64.2, F64.9

**References**

1. AHFS. Available by subscription at <http://www.lexi.com>
2. DrugDex. Available by subscription at <http://www.micromedexsolutions.com>
3. Fensolvi (leuprolide acetate) Prescribing Information. Tolmar Pharmaceuticals, Inc., Fort Collins, CO: 9/2025.
4. Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, Rosenthal SM, Safer JD, Tangpricha V, T'Sjoen GG. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.
5. World Professional Association for Transgender Health Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 8). 2022. Available at: <https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644>

**Review History**

Date of Last Annual Review: 2Q2026

Changes from previous policy version:

- No clinical change to policy following annual review.

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*